REMARKS/ARGUMENTS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claims 3, 8, 10 and 13 have been amended. Claims 23-25 have been added, and claims 7, 10, 11 and 15 have been cancelled herein.

Applicants' attorney apologizes for the inadvertent errors relating to claim numbering and presentation appearing in the January 15, 2004 Amendment and Response. The present document contains a corrected Listing of Claims, to date.

Further, Applicants' attorney sincerely apologizes for the inadvertent errors in the Rule 131 Declaration filed on July 25, 2003. Another Rule 131 Declaration is attached hereto which remedies the deficiencies and errors present in the prior Declaration.

Rejection of Claims 3 and 10 Under 35 U.S.C. 112, First Paragraph

The Examiner has rejected claims 3 and 10 under Section 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skill in the art to make and/or use the invention. In particular, the Examiner contends that no basis for cell lines 107-35-53 and 110-81-17 can be located in U.S. Patent No. 5,753,430.

In response, Applicants submit that a Declaration is attached, signed by co-inventor Dr. Scott Muerhoff, which establishes the equivalency between the monoclonal antibodies referenced in the patent and those of the present application (i.e., 107-35-54 = H35C54 and 110-81-17 = H81C17). Thus, in view of the Declaration, it is submitted that the Section 112, first paragraph rejection of claims 3 and 10 has been overcome and should be withdrawn accordingly.

Rejection of Claims 1-6 Under 35 U.S.C. 102(b)

The Examiner has rejected claims 1-6 under Section 102(b) as being anticipated by WO 00/07023. In particular, the Examiner contends that WO 00/07023 teaches a simultaneous assay for HCV core antigen and HCV antibodies using an antigen that includes core epitopes that do not bind the antibodies used to detect HCV core antigen, where the antigen and antibodies are immobilized on the same solid phase, and where the monoclonal antibodies include C11-14, C11-10, C11-3 and C11-7.

In response, Applicants submit that the Examiner's concerns, giving rise to the rejection, have been adequately addressed by the claim amendments shown above. The cited reference does not disclose the claimed invention. Thus, it is respectfully submitted that the Section 102(b) rejection of claims 1-6 is now moot and should be withdrawn accordingly.

Two Maintained Rejections of Claims 1, 2, 4, 13 and 14 Under 35 U.S.C. 102(e)

The Examiner has maintained the rejection of claims 1, 2, 4, 13 and 14 under Section 102(e) as being anticipated by U.S. Patent Publication No. 2002/0192639 A1 (Chien et al.) and the rejection of claims 1, 2, 4-6, 13 and 14 under Section 102(e) as being anticipated by U.S. Patent Publication No. 2003/0049608 A1 (Bahl et al.).

In response, a Rule 131 Declaration is attached hereto establishing that the claimed subject matter was conceived of and reduced to practice in the United States prior to the provisional application filing dates of both the Chien et al. and Bahl et al. documents. Thus, the Section 102(e) rejections have been overcome and should be withdrawn accordingly. The cited documents do not anticipate the claimed invention.

Rejection of Claims 13 and 14 Under 35 U.S.C. 102(e)/103(a)

The Examiner has rejected claims 13 and 14 under Section 102(e) as anticipated by or, in the alternative, under Section 103(e) as obvious over WO 00/07023. In particular, the Examiner contends that the composition of WO 00/07023 is believed to anticipate the subject matter of claims 13 and 14, although it is not explicitly referred to as a "kit" but if not, it would have been obvious to package the composition in the form of a kit as is conventionally done for reasons of convenience and economy.

In response, Applicants submit that the claimed invention is not disclosed by the cited reference. Furthermore, one of ordinary skill in the art certainly would not have been motivated to have utilized at least one of the precise monoclonal antibodies recited in claim 13 in order to create the claimed kit; thus, the claimed kit itself that encompasses one or more specific antibodies is neither taught nor suggested by the cited reference.

In view of the above, it is submitted that the Section 102(e)/Section 103(a) rejection of claims 13 and 14 has been overcome and should be withdrawn accordingly. The claimed invention is neither taught nor suggested by the cited reference.

Rejection of Claims 7, 8-11 and 15 Under 35 U.S.C. 103(a)

The Examiner has rejected claims 7, 8-11 and 15 (now claims 8 and 9) under Section 103(a) as being unpatentable over WO 00/07023. In particular, the Examiner contends that WO 00/07023 discloses a composition and method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody using at least one HCV antigen and at least one HCV antibody, which may be C11-3, C11-7, C11-10 and/or C11-14, coated on a single solid phase, and using conjugates comprising antibodies attached to the same signal-generating compound and detecting the generated signal. Further, the Examiner notes that the method of WO 00/07023 differs from the

claimed method only by exemplifying the use of an enzyme label in place of a chemiluminescent label such as acridinium and by not exemplifying use of a microparticle as a solid phase. Further, the Examiner contends that it would have been obvious to one of ordinary skill in the art, based upon the teachings of WO 00/07023, to have used a chemiluminescent label because WO 00/07023 teaches that any conventional label may be used. Also, the Examiner contends that it would also have been obvious to use a microparticle as a solid phase for immobilizing the antigen and antibody because WO 00/07023 teaches that any immunoassay solid phase carrier may be used.

In response, Applicants submit that the one of ordinary skill in the art certainly would not have been motivated to have created the claimed invention of claims 8 and 9 based upon the teachings or suggestions of the cited reference. In particular, the Examiner will note that Example 6 of WO 00/07023 (see equivalent U.S. published patent application no. 6,623,921) discloses the use of monoclonal antibody C11-3 and monoclonal antibody C11-7 on the solid phase and monoclonal antibody C11-14 in the conjugate. In contrast, the claimed method recites the use of monoclonal antibody C11-14 on the solid phase and monoclonal antibody C11-10 in the conjugate (see claim 8, as amended). Thus, based upon the teachings and suggestions of WO 00/07023, one of ordinary skill in the art certainly would not have been motivated to have utilized the recited monoclonal antibody combination of the claimed method.

Further, the data presented in table on page 47 of the specification (entitled Detection of HCV Core Protein by Monoclonal Antibodies) indicate that new and unexpected results are obtained when one utilizes the monoclonal antibody combination of the present invention as compared to that of Example 6 of the reference. More

specifically, the table shows that when C11-14 is utilized on the solid phase and C11-10 is used in the conjugate in the simultaneous detection assay of the present invention (see claim 7), a P/N of 32.04 results. However, in comparison, the table also shows that when C11-3 and C11-7 are used on the solid phase and C11-14 is used in the conjugate (i.e., the combination disclosed in WO 00/07023), a P/N of only 1.98 results. Thus, utilizing the claimed combination, one obtains new and unexpected results that could never have been foreseen based upon the teachings and suggestions of WO 00/07023. (Such an assertion may be placed in the form of a Rule 132 Declaration should the Examiner so desire.) Additionally, lines 15-17 on page 47 of the specification indicate that "[c]learly, in our format the best condition is to use C11-14 Mab on the solid phase and C11-10 on the conjugate side of the assay".

In view of the above, it is submitted that claims 8 and 9 are not are not obvious over the cited reference. One of ordinary skill in the art certainly would not have been motivated to have carried out the claimed method in view of the teachings and suggestions of the cited reference. The claimed method yields new and unexpected results. Thus, it respectfully submitted that the Section 103(a) rejection has been overcome and should be withdrawn accordingly.

Rejection of Claims 7-11 and 15 Under 35 U.S.C. 103(a)

The Examiner has maintained the rejection of claims 7-11 and 15 (now claims 8 and 9) under Section 103(a) as being unpatentable over Chien et al. In particular, the Examiner contends that it would have been obvious based upon the teachings of Chien to have used a microparticle as a solid phase for immobilizing antigens and antibodies

because Chien teaches that any conventional immunoassay solid phase may be used for that purpose.

In response, Applicants submit that the attached Rule 131 Declaration establishes that the claimed invention was conceived of and reduced to practice prior to the priority provisional filing date of Chien et al. Thus, it is submitted that the Section 103(a) rejection has been overcome and should be withdrawn accordingly.

Rejection of Claims 8-12, 14 and 15 Under 35 U.S.C. 103(a)

The Examiner has rejected claims 8-12, 14 and 15 (now claims 8, 9 and 14) and under Section 103(a) as being unpatentable over Bahl et al. in view of Chien et al. In particular, the Examiner contends that it would have been obvious to one of ordinary skill in the art to have substituted a chemiluminescent label as taught by Chien for the exemplified enzyme of Bahl et al. because Bahl et al. requires only a "detectable label" and because Chien teaches that any conventional label, including a chemiluminescent label, can be used in an HCV antigen-antibody combination assay.

In response, Applicants attach hereto a Rule 131 Declaration (as described above) which establishes that the claimed invention was conceived of and reduced to practice in the United States prior to the provisional application filing dates of both Chien and Bahl. Thus, in view of the Declaration, the Section 103(a) rejection has been overcome and should be withdrawn accordingly.

It is believed that the subject application is in condition of allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning this matter, she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,
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